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Elena S. Polovnikova, Ph.D.
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COMMENTS

The facsimile confirmation of the Patent Office imprinted hereon will acknowledge receipt of:

Serial No: **09/807,809**
Filing Date: **July 30, 2001**
Applicant: **Robert David POSSEE et al.**
For: **Baculovirus Expression System**
Papers Submitted: **Transmittal; Notice of Appeal; PTO-2038; Pre-Appeal Brief Request for Review**
Docket No.: **46309/257438**
Date Mailed **November 9, 2006**
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PATENTS

IN THE U.S. PATENT AND TRADEMARK OFFICE

In re Application of:
Robert David Possee, et al.
Serial No. **09/807,809**
Filed: **July 30, 2001**
For: **Baculovirus Expression System**

Docket No. **46309-257438**

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith is a paper in the above-identified application.

- ☒ Notice of Appeal.
- ☒ Pre-Appeal Brief Request for Review
- ☒ PTO-2038.
- ☐ Applicant claims small entity status.
- ☐ Additional fee is calculated below.

					SMALL ENTITY		OTHER THAN SMALL ENTITY	
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADDIT. FEE	RATE	ADDIT. FEE
TOTAL	8	MINUS	50=	0	x9	$	x18	$
INDEP.	1	MINUS	3=	0	x42	$	x84	$
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIMS					+140	$	+280	$
				TOTAL ADDITIONAL FEE		**$ 0**		**$**

☒ The Commissioner is hereby authorized to charge any additional fees required under 37 CFR §1.16, or credit any overpayment, to Account No. 11-0855. A duplicate copy of this sheet is enclosed.

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By: Elena S. Polovnikova, Ph.D. – Reg. No. 52,130
Reg. No. 42,860

DOCKET NO. 46309-257438

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Robert David Possee et al.

Serial No. **09/807,809**
(National Phase of PCT/GB00/03114)

Filed: **July 30, 2001**

For: **BACULOVIRUS EXPRESSION SYSTEM**

Examiner: **Marvich, Maria**

Art Unit: **1636**

PRE-APPEAL BRIEF REQUEST FOR REVIEW

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P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Responsive to the Office Action dated January 13, 2006 ("Office Action"), and the Final Office Action dated August 9, 2006 ("Final Office Action"), Applicants request a pre-appeal brief review in the application identified above. A concise statement setting forth the reasons for the request is set forth below.

REASONS FOR THE REQUEST

In the Office Action and the Final Office Action, the Examiner has failed to establish a *prima facie* basis for rejecting Claims 27-34 under 35 U.S.C. §103(a), as obvious over U.S. Patent No. 6,911,206 to Campos *et al.* ("Campos") in view of U.S. Patent No. 5,348,886 to Lee *et al.* ("Lee"), and further in view of Merrington *et al.*,

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Elena S. Polovnikova, Ph.D. – Reg. No. 52,130

US2000 9572806.1

Virology, v. 217, pp. 338-348 (1996) ("Merrington"). This is the only remaining rejection in this case.

Applicants' method, as claimed, uses a circular, naked, replication-deficient and capable of being maintained in a bacterial cell baculovirus vector for recombination with a rescue vecor. The Examiner has argued that Campos disclosed a method that uses a circular, naked replication-deficient baculovirus vector, which can be modified with the bacterial replicon and a selectable marker as taught in Lee and with a mutated lef-2 gene taught in Merrington to render it replication-deficient. The Examiner asserted that such a modification would result in Applicants' method, as claimed.

Applicants assert that the Examiner erroneously concluded that Campos disclosed a method that uses a circular, naked replication-deficient baculovirus vector for recombination. Campos does not teach, suggest or provide motivation to derive a method that uses a circular, naked, replication-deficient baculovirus vector for recombination with a rescue vector. On the contrary, Campos teaches a method that uses a baculovirus vector, which Campos refers to as baculovirus DNA, that is linearized before recombination. Campos does not teach a limitation recited in the pending claims. Thus, modifying the baculovirus DNA in Campos with the elements taught in Merrington and Lee, as interpreted by the Examiner, would not and could not result in Applicants' method, as claimed.

Merrington or Lee, separately or in combination, also fail to teach, suggest, or provide motivation to derive a circular, naked, replication-deficient baculovirus vector. Since Campos, Merrington, and Lee fail to teach, suggest, or provide motivation to derive all elements of Applicants' claimed method, they fail, separately or in combination, to render the claims *prima facie* obvious. Applicants respectfully request the review of the Examiner's erroneous rejection in view of the Remarks set forth below and in view of the previous arguments by Applicants.

REMARKS

Applicants traverse the rejection of Claims 27-34 under 35 U.S.C. §103(a) as unpatentable over Campos in view of Lee, and further in view of Merrington. Applicants assert that the publications cited by the Examiner fail to render Claims 27-34 obvious at least because the cited publications, separately or in combination, fail to teach, suggest or provide motivation to derive a method that uses a naked, circular and capable of being maintained in a bacterial cell baculovirus vector for recombination with a rescue vector. Please see Applicants' "Amendment and Response to Office Action" filed May 15, 2006, the section entitled "Rejections under 35 U.S.C. § 103(a)," which appears at pages 5-10, where Applicants' arguments are more fully set forth.

In particular, the Examiner asserted in the Office Action that Campos, in column 33, line 35 through column 34, line 36 (Example 4), disclosed an element recited in the pending claims, recombination of a naked, circular, replication-deficient baculovirus vector with a rescue or transfer vector. The Examiner presumed that the vector in Campos was circular before recombination with a rescue or transfer vector because Campos did not teach the linearization of baculovirus DNA prior to recombination.

Applicants assert that Campos, in fact, discloses a replication-deficient viral DNA that is linearized before recombination, and is sold in linearized form, so that the user does not perform the linearization step. Specifically, Campos only teaches the use of baculovirus BacPAK DNA, which is linearized by its commercial supplier, Clontech, and is therefore linear and not circular before recombination with the rescue or transfer vector in the insect cells. Campos does not teach and could not be interpreted to teach or suggest recombination of the naked, circular, replication-deficient baculovirus vector recited in the pending claims.

The Examiner's determination that Campos teaches recombination of a naked, circular replication-deficient baculovirus vector is erroneous. Campos contains ample evidence that it uses BacPAK baculovirus DNA. Specifically, Campos teaches the use of

the Clontech BacPAK system in all specific examples of baculovirus expression: in Column 20, lines 10-14, examples of transfer vectors are pBacPAK8 and pBacPAK9 (Clontech), or pBAK-based fusion vector; in Column 33, Example 4, the transfer vector used to place the foreign coding regions under control of the polyhedrin gene promoter is pBacPAK9 (Clontech); in Column 33, Example 4, Campos uses the replication-deficient virus DNA that contains "homologous flanking viral sequences present in pBacPAK9." Thus, the replication-deficient virus DNA in Campos is BacPAK baculovirus DNA.

As Applicants previously brought to the Examiner's attention, BacPAK system uses linearized viral DNA, and Clontech provides BacPAK baculovirus DNA in a linearized form. Applicants previously submitted evidence to that effect. Please see Exhibit A to "Amendment and Response to Office Action" filed May 15, 2006. Accordingly, Campos teaches using linearized baculovirus DNA for recombination with a rescue vector, and not circular baculovirus DNA. Campos does not teach, suggest, or provide motivation to use any baculovirus DNA other than BacPAK.

In the Final Office Action, the Examiner agrees that the viral recombination sequences in Campos are BacPAK recombination sequences (see Campos, column 20, lines 50-55), but disagrees that the replication deficient baculovirus DNA in Campos was BacPAK. Applicants assert that this conclusion is erroneous. BacPAK recombination sequences in the transfer vector are employed to transfer the gene expression cassette from pBacPAK-based transfer vectors into BacPAK baculovirus DNA. BacPAK recombination sequences are present in the pBacPAK9-based transfer vector in Campos precisely so that the vector could recombine with BacPAK baculovirus DNA, also containing these BacPAK recombination sequences. Thus, the baculovirus DNA in Campos is BacPAK, and BacPAK baculovirus DNA is linearized before recombination.

The Examiner states in the Final Office Action that the fact that Campos teaches digesting the transfer vector but not the baculovirus DNA supports the conclusion that the baculovirus DNA in Campos stays circular. Applicants assert that this conclusion is also erroneous. On the contrary, Campos does not teach linearization of baculovirus DNA

because BacPAK DNA is sold in linearized form. The reason that Campos does not teach digesting it prior to recombination is because BacPAK baculovirus DNA has already been digested by its commercial supplier for the use in protocol described in Campos. Thus, lack of teaching of the linearization step in Campos supports the conclusion that the baculovirus DNA is linearized BacPAK DNA.

In view of the foregoing, Applicants assert that Campos fails to teach, suggest, or provide motivation to derive the naked, circular, replication-deficient vector used for recombination in the claimed method. Campos, alone or in combination with Merrington and Lee fails to teach, suggest, or provide motivation to derive all elements of applicants' claimed method, and fails to render the claims *prima facie* obvious. Applicants respectfully request withdrawal of the rejection of Claims 27-34 under 35 U.S.C. §103(a).

CONCLUSION

For the reasons set forth above, Applicants respectfully request that the pending claims be allowed.

Respectfully submitted,

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